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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/722,471	11/28/00	MCCULLOUGH	4821-405

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EXAMINER

COOK, R

ART UNIT

1614

PAPER NUMBER

DATE MAILED: 05/16/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/722,471

Applicant(s)

McCullough et al

Examiner

Rebecca Cook

Art Unit

1614



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above, claim(s) 1-15, 30-42, and 56-78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-29 and 43-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 20) ☐ Other:

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15, drawn to a method of treating pain, classified in class 514, subclass 649.
- II. Claims 16-29, 43-55 drawn to a method of treating nicotine addiction, classified in class 514, subclass 649.
- III. Claims 30-42, drawn to a method of treating a chronic disorder, classified in class 514, subclass 649.
- IV. Claims 56-68, drawn to a method for treating weight gain, classified in class 514, subclass 649.
- V. Claims 69-78, drawn to a pharmaceutical composition, classified in class 514, subclass 649.

The inventions are distinct, each from the other because of the following reasons: the method of groups 1-IV are separate and distinct and capable of supporting separate patents.

Inventions of Group V and Groups 1-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in materially different processes of using that product as evidenced by the four distinctly claimed methods of use.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Max Bachrach on May 15, 2001 a provisional election was made with traverse to prosecute the invention of Group II, claims 16-29 and 43-55. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-15, 30-42, 56-78 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

To further prosecution applicants are requested to cancel the non-elected claims.

Applicants are requested to update the continuing information.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claims 16-29 and 43-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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It is not clear how much (+)-stereoisomer the recitation "substantially free of its (+)-stereoisomer" is intended to exclude and the specification does not define this. *maintain  
can be 51%.*

In claim 17 the recitations "amount being sufficient to alleviate nicotine addiction" and "amount being sufficient to achieve smoking cessation or a reduction in smoking" are confusing, since it not clear if "amount" refers to the (-)-bupropion or the (+)-stereoisomer. If it refers to the (-)-bupropion it is not clear why the claims recite "insufficient to cause adverse effects associated with the administration of racemic bupropion", since on page 9 the specification discloses that (-)-bupropion avoids adverse effects associated with racemic bupropion. This implies that it is the (+)-stereoisomer that causes the adverse effects.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16-29, 43-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over applicants' admission on page 2 that the method of using bupropion to treat smoking addiction and aid in smoking cessation is known in view of Coutts et al (CL).

The claims differ over applicants' admission in requiring (-)-bupropion.

However, Coutts et al disclose that different enantiomers possess different pharmacodynamic properties and that the desired therapeutic effect may reside in one enantiomer while the undesirable toxic effects may reside in the other.

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In the absence of a showing in Declaration form of unobvious results commensurate in scope with the claims it would be obvious to one of ordinary skill in the art to use the therapeutically active enantiomer of bupropion. One would be motivated by the desire to avoid the enantiomer which had the undesirable toxic effects.

Applicants are requested to submit an IDS. Coutts et al was not provided since applicants submitted it with the IDS for the parent case.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (703) 308-4724. The examiner can normally be reached on Monday through Friday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
REBECCA COOK  
PRIMARY EXAMINER  
GROUP 1200

May 15, 2001